**Remarks**

After entry of the amendment, claims 36-55 are pending.

Claims 1-35 have been canceled without prejudice.

New claims 36-55 have been added and are supported by the originally filed claims and the specification at, for example, page 27, lines 1-5; page 28, line 19 to page 29, line 20; and page 30, line 22 to page 31, line 4.

Because this application was filed as a continuation-in-part application, a new Declaration signed by the inventor(s) must be submitted to the US Patent Office pursuant to 37 CFR § 1.63(e). The PTO never requested a new Declaration. In view thereof, Applicants are filing herewith a new Declaration executed by the inventor. The Declaration does not make any claim to priority. In view thereof, the "Related Applications" paragraph has been deleted from the specification at page 1, lines 2-9.

No issues of new matter should arise and entry of the amendment is respectfully requested.

**Rejection under 35 U.S.C. § 102**

Claims 10, 14-19 and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/43675.

Applicant respectfully traverses the rejection and respectfully submits that the claimed invention is not anticipated by WO 98/43675. The PTO has also referenced CA129:293908 which is a very short excerpt taken from WO 98/43675. Because WO 98/43675 is in Japanese and CA129:293908 is a very short excerpt from WO 98/43675, Applicant has taken the liberty of analyzing European Application No. 0 974 366 (a copy of which is cited and provided in the Information Disclosure Statement filed concurrently herewith) which is the corresponding European application to WO 98/43675 and CA129:293908.

EP 0 974 366 teaches formulations comprising a medicine and an anionic high molecular substance, such as carrageenan, to prevent the formulation from having an unpleasant taste (*see* EP 0 974 366 at Abstract; WO 98/43675 at Abstract). The anionic high molecular substances are polymers, such as carrageenan, chondroitin sulfate, dextran sulfate, alginic acid, gerun gum, and xanthan gum (*see* EP 0 974 366 at ¶ 7). EP

0 974 366 does not disclose or suggest that polyvinylpyrrolidone is an anionic high molecular substance that will mask the unpleasant taste of the formulation.

The only reference to polyvinylpyrrolidone in the entire disclosure in EP 0 974 366 and CA129:293908 is in Example 1. More particularly, Example 1 discloses a formulation comprising donepezil, sodium saccharin, κ-carrageenan (i.e., an anionic high molecular substance to mask the unpleasant taste of the formulation), 12% by weight povidone, methylparaben, propylparaben, and purified water. The present pending claims recite formulations comprising no more than 3% by weight polyvinylpyrrolidone. Because the amount of povidone described in EP 0 974 366 is significantly greater than the amount of povidone recited in the pending claims, EP 0 974 366, WO 98/43675, and CA129:293908 cannot anticipate the pending claims and cannot render the pending claims obvious.

In view thereof, Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) be withdrawn.

**Rejection under 35 U.S.C. § 103**

Claims 1-35 are rejected as being obvious over WO 98/43675.

Applicant respectfully traverses the rejection and respectfully submits that the claimed invention is not obvious over WO 98/43675. The PTO has also referenced CA129:293908 which is a very short excerpt taken from WO 98/43675. Because WO 98/43675 is in Japanese and CA129:293908 is a very short excerpt from WO 98/43675, Applicant has taken the liberty of analyzing European Patent Application No. 0 974 366 (a copy of which is cited and provided in the Information Disclosure Statement filed concurrently herewith) which is the corresponding European application to WO 98/43675 and CA129:293908.

EP 0 974 366 teaches formulations comprising a medicine and an anionic high molecular substance, such as carageenan, to prevent the formulation from having an unpleasant taste (*see* EP 0 974 366 at Abstract; WO 98/43675 at Abstract). The anionic high molecular substances are polymers, such as a carrageenan, chondroitin sulfate, dextran sulfate, alginic acid, gerun gum, and xanthan gum (*see* EP 0 974 366 at ¶ 7). EP

0 974 366 does not disclose or suggest that polyvinylpyrrolidone is an anionic high molecular substance that will mask the unpleasant taste of the formulation.

The only reference to polyvinylpyrrolidone in the entire disclosure in EP 0 974 366 and CA129:293908 is in Example 1. More particularly, Example 1 discloses a formulation comprising donepezil, sodium saccharin, κ-carrageenan (i.e., an anionic high molecular substance to mask the unpleasant taste of the formulation), 12% by weight povidone, methylparaben, propylparaben, and purified water. The pending claims recite formulations comprising no more than 3% by weight polyvinylpyrrolidone.

Because the amount of povidone described in EP 0 974 366 is significantly greater than the amount of povidone recited in the pending claims, EP 0 974 366 does not render the pending claims obvious. Neither EP 0 974 366 nor CA129:293908 provide any reason why povidone was included in the formulation of Example 1. There is absolutely no reference to povidone anywhere else in the specification. Nor do these references provide any motivation or suggestion to significantly reduce the amount of povidone in the formulation from 12% to the presently claimed amount of 3%.[1] Therefore, one skilled in the art would not have any reason or motivation to significantly reduce the amount of povidone in the formulation to arrive at the presently claimed invention.

In view thereof, Applicant respectfully requests that the rejection under 35 U.S.C. § 103 be withdrawn.

**Information Disclosure Statement**

Applicant is filing an Information Disclosure Statement concurrently herewith. With respect to the comments on page 3 in the Office Action, Applicant notes that WO 97/46527 corresponds to US Patent Nos. 6,140,321 and 5,985,864; WO 01/66096 corresponds to US Publication No. 2003/0144255; and WO 98/39000 corresponds to US Patent No. 6,455,544 and US Publication No. 2003/0055040.

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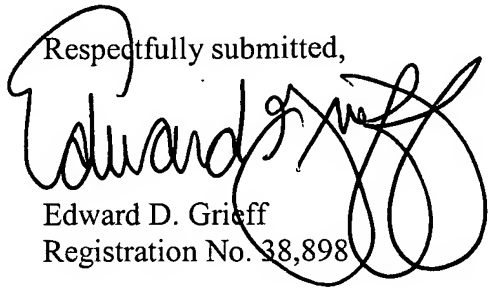
[1] Even if the purpose of using povidone was to mask the unpleasant taste of the formulation (for which there is no evidence in EP 0 974 366 or CA129:293908), one skilled in the art would not be motivated to reduce the amount of povidone from the 12% in Example 1 to the presently claimed amount of 3%. Such a significant reduction would lead one skilled in the art to believe that the unpleasant taste would return to the formulation (again assuming that the reason for using povidone was to mask the unpleasant taste, for which there is no evidence in EP 0 974 366 or CA129:293908).

**Conclusion**

An early and favorable reconsideration and allowance of pending claims 36-57 is respectfully requested.

Respectfully submitted,



Edward D. Grieff
Registration No. 38,898

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Venable LLP
575 7th Street, NW
Washington, DC 20004
Phone: 202-344-4382
Fax: 202-344-8300